Section A: General Information

Summary and Report

Description	Date(s)
Internal Audit Main Event (1-2 weeks)	May 24, 2017 to July 24, 2017
Internal Audit Main Event Closing Meeting	Scheduled to coincide with the monthly and/or annual management review (AMR) in October 2017
Report Submit to CRL Directors	08/04/17 (mid-year) and 05/25/18 (completion)

Note: The *Internal Audit Main Event Closing Meeting* does not apply to this QSA since the CRL QA Coordinator (with some assistance) performed the entire audit. Management is notified of all audit findings through the monthly QA-Management monthly meetings. CRL staff members are notified with a summary of the audit during the monthly QA lab-wide meeting. Individuals (observed analysts) participating in the audit are notified of any findings as they were discovered.

Title	Audit Function	Name	Position	Experience
Lead Assessor	ISO 17025, Section 4, Reviews, Reports	Angela Ockrassa Davis	QA Coordinator	Internal system and SOP audits
Assessor 1	ISO 17025: 2002 Section 5	Angela Ockrassa Davis	QA Coordinator	Same as above
Assessor 2	ILAC G19: 2002 Forensic Science	Angela Ockrassa Davis	QA Coordinator	Same as above
Assessor 3	SOP Activity Witnessing SOP activity	Angela Ockrassa Davis Amanda Wroble Kristen Leckrone	QA Coordinator Metals GL Organics & DW	Same as above *Overseen by QAC *DW cert officer

Note: All assisting assessor are overseen by the Lead assessor.

Section B: Findings Summary

	Audit Description	Y/N	[1]Finding(s)	[2]Workflow ID(s)
1	Were previous year CA(s) implementation and/or effectiveness confirmed?	Y/N	Concern QSA01	See section C
2	Was CRL checklist 004-A, Internal system audit for ISO 17025 components, completed?	Y	4 N/C, 5 concerns, 4 comments	See section C with its associated finding
3	Was CRL checklist 004-B, Internal system audit for ILAC G-19 (CIS) components, completed?	Y	0	Doc #10264
4	Was CRL checklist 004-C, Internal SOP activity audit(s) for witnessing, completed?	Y	multiple	See page 4
5	Follow up audit recommended/scheduled?	N	n/a	See page 4
6	Concerns/comments/recommendations provided?	Y	various	See page 4
7	Deficiency findings identified?	Y	See page 4	See page 4

[1] State the number of finding(s) base on deficiencies unless otherwise specified.

[2] Qualtrax workflow IDs: CAR or Task (Request)

*Note: SOP audits (witnessing and technical data reviews) are completed throughout the calendar year so their associated findings are to be determined (TBD). This report is generated mid-year (for ISO 17025, Forensics, and general internal system audit) and end-year (to including SOP audits) for completion.

Acronyms and Definitions

Comment: A finding about documents or practices with a potential of improvement; but still fulfilling the requirements. Any comments found during this audit are summarized at the end of this report.
Concern: A finding where, in the opinion of the audit team, the practice may develop into a noncompliance or nonconformity. Any concerns discovered during this audit are summarized following this section.

Finding: An audit conclusion referenced to a requirement and supported by objective evidence that identifies compliance with and/or a deviation from the requirement. NOTE: Lack of evidence identifying compliance with a requirement is a finding.

Non-compliance: A finding where the documents or practices do not meet the requirements of the ISO 17025 standards, the SOPs, the QMP, or other regulatory programs in a way that jeopardizes the quality of work. Any non-compliances discovered during this audit are summarized following this section.
Non-conformance: A finding that lacks in characteristic, documentation or procedure rendering the quality of the item or activity unacceptable. A technical finding can be a type of non-conformance. Any non-conformances discovered during this audit are summarized following sections.

Section C: Finding Descriptions

ISO and general internal QSA findings**:**

-- Comments –

Past internal QSA and audit findings reviewed. No comments other than the fact that CA are taking a long time to close out.

ISO comment 01: ISO section 4.12.2 verified on 07/10/17 via CA #3741. Comment 01: QA-WI019 section 2.8 could be more specific in its instructions to note/highlight applicable controls to ensure effectiveness. *Resolution: See TASK #10984.*

ISO comment 02: ISO section 4.13.1.1 verified SOP QA documents (6.4.2, 9.4.2 9.4.5) via Qualtrax # 894 on 07/10/17. Technical records (6.4.1), COC (6.5), and tags (6.6) verified on 07/11/17 with WO #1604015 (tech records & COC) and WO #1105002 (tags). Comment 02: Most, if not all, of the cited QMP section could be relocated to SOP GEN018. *Resolution: See TASK #10984.*

ISO comment 03A: ISO section 5.4.3 checked on 07/20/17. Comment 03A: The following part of this requirement is not directly addressed in the QMP: “assigned to qualified personnel equipped with adequate resources.” It should include group meeting; assigned party; documented in group schedule. Address during the annual QMP revision.

ISO comment 03B: ISO section 5.4.3 checked on 07/20/17. Comment 03B: The following part of this requirement is not directly addressed in the QMP: "assigned to qualified personnel equipped with adequate resources." It should include group meeting communication. Address during the annual QMP revision. *Resolution: See TASK #10984.*

ISO comment 04 (CRL CHKLST 004-A "comment 02" as well): ISO section 5.3.2 verified on 07/19/17 via ELPRO log in G drive: File 007892_EPA lab 1003 S1=ENV -20170328-01.MDF Comment 02: Records for Elpro are backed up in the G drive where they can accidently be deleted. A better back-up location would be the I drive. *Resolution: See TASK #10983.*

-- Concerns –

Concern QSA01: Two (2) of the ten (10) internal QSA non-compliances remain open to date pending CA implementation (CA #9279) and/or investigation (10014). In reviewing past CAs in the system, it appears on average 20% of all CA remain open way passed the required 45-TAT documented in the pertinent CA work instruction. Two (2) CA entries in the system date back to 2015: CA #4981 & #6715.

ISO Concern 01: ISO section 4.11.5 Checked on07/10/17. The note under QMP section 9.10.2.5 states "The incident response and/or clarification (by the CRL Deputy Director and/or Client) will be applied before impacted samples are made available for analysis" but that is not always possible. In some few cases, the sample need to be released to for analysis asap due to sampling hold times and should be included within this paragraph. *Resolution: See CA #10500.*

ISO Concern 02: ISO section 4.13.1.2. The retention record schedules associated with purchase card records and monitoring projects are not addressed anywhere (QMP or GEN018).
Resolution: See CA #10972.

ISO Concern 03: ISO section 5.3.5 verified on 07/19/17 via lab walk through in the inorganic section. Concern 03: The monthly lab walk-through performed by the CHO should be included in the QMP (in this section; 8.5.2) as it addresses the requirement since she reports housekeeping issues. Her emails should also be included in Qualtrax as they are records which document the procedure and findings.
Resolution: See TASK #10984.

ISO Concern 04: ISO section 5.4.2 checked on 07/19/17. Concern 04: QMP section 9.4.4.3 states that "CRL shall check the daily Federal Register notices pertaining to 40 CFR part 136 for updates" CRL does not check the Federal Register daily. This documentation should be revised to reflect current practice: CRL analysts check for method reference updates during annual SOP revision cycles (routinely every winter) and are notified by the Deputy Director once a MUR is released.
Resolution: See TASK #10984.

ISO Concern 05: ISO section 5.4.5.2 verified on 07/20/17 via WO #1612003-009 (in-process). Concern 05: QA-WI009 currently does not provide instructions to attach validation documentation or any evaluation criteria in the DOC workflow instance submitted for approval. CRL very rarely performs validation, but these missing instructions should be included.
Resolution: See TASK #10985.

-- Non-Compliances –

ISO Non-compliance 01: ISO section 4.3.2.2 d) Checked and verified as a non-compliance 01 on 06/05/17. Contrary to the cited QMP v4 statement regarding retired documents, CRL retired QA document headers does not display a "retired" status. Instead it still displays "published." See example: QA-WI003 v6.
Resolution: See CA #10964.

ISO Non-compliance 02: ISO section 4.13.1.2 verified on 07/12/17 for QA records (6.4.2.1) via Qualtrax record disposition ID 10751. Noncompliance 02: Although retention records are established for judicial/non-judicial records (4.4.3-6.4.4), their associated procedure is not being followed. According to SOP GEN018 §10, "Current files are kept in the Data Custody Room for 2 years prior to the current year as well as the current year. All files prior to those three years are archived to the Federal Records Center (FRC)." However, CRL has files dating way passed this time frame and go back as far as 20 years. Other instructions documented in this section(s) are also not a reflection of the current practice. Collectively, they are all deviations against internal procedure (GEN018).

ISO Non-compliance 03: ISO section 5.2.2 checked on 07/18/17 via Qualtrax training ID 530. Noncompliance 03: "The effectiveness of the training actions taken shall be evaluated" is not define at CRL nor addressed in the QMP.
Resolution: See CA #10974.

ISO Non-compliance 04: AB requirement for control and use of accreditation symbol was verified as a non-compliance on 07/24/17 via WO #1506005 (NC) although 1212016 (C), 1212006 (C), 1204008 (C) were compliant. The very last report that was released for CIS work did not contain the ILAC symbol even though the three reports released before that one did include it.
Resolution: See CA #10975.

SOP Audit findings**:**
For a description of all findings, refer to the audit report/checklist associated with the SOP witnessed. To review the SOP audit schedule and detailed assessment information, including the data provided directly below, refer to document #5467. All deficiency findings are reviewed by QA Coordinator and the deputy director. When needed, both parties plus the laboratory director discuss them during QA-management monthly meetings.

#	Technology	SOP	Analyst	WO #	CA #	Audit Rpt ID#	Comments
1	AA	AIG043D	CB	17,030,141,703,015	12624	12627	task 12626
2	Combustion IR	AIG006A	CB	1710017	no	12107	task 12637
3	Electromagnetic	AIG021D	FA	1708001	12213	12215	interview/no samples in-house
4	Flashpoint	--	--	--	--	--	--
5	GC/MS	GC002	DL	1707010, 12-13	13351	13368	--
5	GC/MS	MS023	MK	1711001, 1711002	13234	13235	--
6	Gravimetric	AIG018	NF	1710020	12578	12114	--
7	ICP	Metals004	KS	1710015	on-the-spot CA	13264	see rpt 4 CA description
8	ICP	AIG032A/AIG033A	AK	100008, 100014	on-the-spot CA	13265	see rpt 4 CA description
8	LC	--	--	--	--	--	--
9	Spectrophotometric	AIG035	NF	1710017	12600	12115	--